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EXAMINER

SKELDING, ZACHARY S

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1644

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/616,760	Applicant(s) GELBOIN ET AL.	
	Examiner ZACHARY SKELDING	Art Unit 1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 June 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 13-15, 18-22, 25, 26, 74-78 and 80-82 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 75 is/are allowed.
- 6) ☒ Claim(s) 13-15, 18-22, 25, 26, 74, 76-78 and 80-82 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

1. Applicant's amendment to the claims filed June 5, 2008 has been entered.

Claims 1-12, 16-17, 23, 24, 27-73, 79 have been canceled.

Claims 13, 76 and 78 have been amended.

Claims 13-15, 18-22, 25-26, 74-78 and 80-82 are pending.

Claims 13-15, 18-22, 25-26, 74-78 and 80-82 are under consideration as they read on a monoclonal antibody that competes with MAb 763-15-5 for specific binding to p450 2C9 allelic variants 2C9*1, 2C9*2, and 2C9*3 either at the same epitope bound by the monoclonal antibody 763-15-5 or wherein the monoclonal antibody inhibits 2C18 catalyzed metabolism of phenanthrene by at least 30%.

2. The rejections of record can be found in the previous Office Action, mailed March 5, 2008.

This Office Action is in response to Applicant's amendment filed June 5, 2008.

A New Grounds of Rejection necessitated by applicant's amendment to the claims is put forth below.

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 13-15, 18-22, 25-26, 74, 76-78 and 80-82 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The previous Office Action mailed March 5, 2008 indicated that previously pending claims 24, 74 and 75 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Applicant asserts that the amendments to the claims submitted June 5, 2008 fulfill this requirement and thus the claims are allowable.

However, previously pending claim 24 recited (emphasis added): “***The monoclonal antibody of claim 13***, wherein the light chain variable domain comprises the three CDR regions ***from the light chain of*** a monoclonal antibody ***MAb 763-15-5 (ATCC PTA- 1079)***, and the heavy chain variable domain comprises the three CDR regions ***from the heavy chain of*** the

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monoclonal antibody *MAb 763-15-5 (ATCC PTA-1079)*,” and base claim 13 recited (emphasis added): “*A monoclonal antibody that competes with a monoclonal antibody MAb 763-15-5* for specific binding to the human cytochrome p450 2C9 allelic variants 2C9*1, 2C9*2, and 2C9*3 at the same epitope bound by the monoclonal antibody MAb 763-15-5, wherein the MAb 763-15-5 inhibits 2C9*1 catalyzed metabolism of phenanthrene and 2C9*2 catalyzed metabolism of phenanthrene wherein binding between the monoclonal antibody MAb 763-15-5 and the human cytochrome p450 2C9 allelic variants 2C9*1, 2C9*2, and 2C9*3 is detectable by an enzyme-linked immunosorbent assay, and wherein MAb 763-15-5 is produced by the hybridoma cell line deposited as ATCC PTA-1079.”

Thus, claim 24, as previously pending read on *the monoclonal antibody of claim 13...*[having] the three CDR regions *from the light chain of* a monoclonal antibody *MAb 763-15-5 (ATCC PTA- 1079)*, and [having] the three CDR regions *from the heavy chain of* the monoclonal antibody *MAb 763-15-5 (ATCC PTA-1079)*.”

The examiner interpreted claim 24 given the plain meaning of the words used and the knowledge of the skilled artisan to refer to a monoclonal antibody that competes with a monoclonal antibody MAb 763-15-5 wherein said monoclonal antibody that competes with a monoclonal antibody MAb 763-15-5 obtains its three light chain CDR regions *from the light chain of* a monoclonal antibody *MAb 763-15-5 (ATCC PTA- 1079)*, and obtains its three heavy chain CDR regions *from the heavy chain of* the monoclonal antibody *MAb 763-15-5 (ATCC PTA-1079)*.”

However, the examiner did not interpret previous claim 24 as simply limiting “the monoclonal antibody MAb 763-15-5” to a monoclonal antibody that obtains its three light chain CDR regions from the light chain of a monoclonal antibody MAb 763-15-5 (ATCC PTA- 1079), and obtains its three heavy chain CDR regions from the heavy chain of the monoclonal antibody MAb 763-15-5 (ATCC PTA-1079), because such an interpretation goes against the plain meaning of the phrase “...wherein the light chain comprises the three CDR regions *from the light chain of* a monoclonal antibody MAb 763-15-5 (ATCC PTA- 1079)...,” in that the skilled artisan would not say that monoclonal antibody MAb 763-15-5 (ATCC PTA- 1079) “comprises the three CDR regions *from the light chain of* a monoclonal antibody MAb 763-15-5 (ATCC PTA-1079)...” as monoclonal antibody MAb 763-15-5 (ATCC PTA- 1079) has these three CDRs to begin with. Moreover, such an interpretation of the claim would also cause it to violate 35 U.S.C. § 112, 4th paragraph in that it would not further limit base claim 13 in that monoclonal antibody MAb 763-15-5 (ATCC PTA- 1079) has these three CDRs to begin with.

In contrast, newly amended claim 13 recites as follows (amended text underlined): “A monoclonal antibody that competes with a monoclonal antibody MAb 763-15-5 for specific binding to the human cytochrome p450 2C9 allelic variants 2C9*1, 2C9*2, and 2C9*3 at the same epitope bound by the monoclonal antibody MAb 763-15-5, wherein the MAb 763-15-5 inhibits 2C9*1 catalyzed metabolism of phenanthrene and 2C9*2 catalyzed metabolism of

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phenanthrene, wherein binding between the monoclonal antibody MAb 763-15-5 and the human cytochrome p450 2C9 allelic variants 2C9* 1, 2C9*2, and 2C9*3 is detectable by an enzyme-linked immunosorbent assay, and wherein MAb 763-15-5 is produced by the hybridoma cell line deposited as ATCC PTA-1079, and wherein the light chain variable domain comprises the three CDR regions from the light chain of a monoclonal antibody MAb 763-15-5 (ATCC PTA- 1079), and the heavy chain variable domain comprises the three CDR regions from the heavy chain of the monoclonal antibody MAb 763-15-5 (ATCC PTA- 1079).”

In contrast to previously pending claim 24 which depended from previously pending claim 13, newly amended claim 13 which applicant asserts incorporated the limitations of previously pending claim 24 is now invalid for indefiniteness because it is insolubly ambiguous. In particular, does “wherein the light chain variable domain comprises the three CDR regions from the light chain of a monoclonal antibody MAb 763-15-5 (ATCC PTA-1079)...” refer to “the monoclonal antibody that competes” or “the monoclonal antibody MAb 763-15-5” itself? If the later then this newly added “limitation” is not really a limitation at all and does not include the limitations of previously pending claim 24 as it was understood by the examiner.

This uncertainty as to the meaning of claim 13 could be resolved, for example, by amending it to include a phrase specifically explicitly linking the phrase “and wherein the light chain variable domain comprises the three CDR regions from the light chain of a monoclonal antibody MAb 763-15-5 (ATCC PTA- 1079)...,” to “said monoclonal antibody that competes.”

The same rejection applies in the same way to newly amended claims 76, 78 and dependent claims thereof.

Thus, the instant claims fail to particularly point out and distinctly set forth the subject matter which applicant regards as the invention, and as a consequence the metes and bounds of the claimed invention are so unclear as to preclude the skilled artisan from ascertaining what would infringe the instantly claimed invention should it issue as a patent.

Given the ambiguity of what is and is not encompassed by currently pending claims 13, 76 and 78, these claims will be interpreted for the purposes of prior art examination as if the newly added limitation does not limit the “monoclonal antibody that competes” but instead simply further describes the MAb 763-15-5 (ATCC PTA-1079) antibody.

Therefore the prior rejections of record under 35 U.S.C. § 102(b) and 35 U.S.C. § 103(a) are hereby maintained for the reasons of record.

5. Claim 75 is allowable.

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6. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).
7. A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.
8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to ZACHARY SKELDING whose telephone number is (571)272-9033. The examiner can normally be reached on Monday - Friday 8:00 a.m. - 5:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eileen O'Hara can be reached on 571-272-0878. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Zachary Skelding, Ph.D.
Patent Examiner
August 31, 2008

/Michail A Belyavskiy/
Primary Examiner, Art Unit 1644